CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 64-081

ADMINISTRATIVE DOCUMENTS

ANDA/AADA OFFICE LEVEL APPROVAL ROUTING SUMMARY

D A F
Apr 23, 1993

ANDA # 64-281
AADA #
Drug Cefaclor Capsules, USP
Usage Form Capsules
Strength 250 mg and 500 mg
Applicant Biocraft Laboratories, Inc.
Proposed Action (AP) TA

REVIEWER:	RECEIPT	ACTION
1. Project Manager Review Support Branch	Date ____ Initials ____	Date 9/16/96 Initials ____ Quest

Original Rec'd date March 3, 1993
Date Acceptable for Filing 4/21/93
Open Amendment Date(s) 7/16/96
Chemistry Reviewer Adams, K.
Supervisor Sherman, J.
Bio Reviewer Mallory, H.
Supervisor Whatley, R.
Date of Office Level Bio Review 12/21/94-LLesko
Pending Legal Case Yes ____ No (X)

EER Status Acceptable 9/13/96
OAI Status Yes ____ No (X)
Patent Certification N/A
Citizen Petition Yes ____ No (X) If YES attach Email from Project Manager to Petition Coordinator of pending approval

Comments:
Application approvable (pending EER) since 10/95. EER is now acceptable. (both NDS & FDS mfg).

2. Director of Chem. I or (II) Office of Generic Drugs	Date ____ Initials ____	Date ____ Initials ____

Comments: Package endorsed by F. Fang 2/8/96. No CMC changes (pre-approval) in the interim. Prior endorsement attached.

3. Office Level Chem Review (1st Generic Only) Div. Dir. of Chem I or II	Date ____ Initials ____	Date ____ Initials ____

Comments:
Multiple generic approvals.

4. P. Rickman Supv., Reg. Support Branch	Date ____ Initials ____	Date ____ Initials ____

Contains certification required by the GDEA if sub after 6/1/92
Yes ____ No ____ //// Determination of involvement? Yes ____ No ____
Paragraph 4 Certification ____ Yes ____ No (checklist)
Comments:
Previously endorsed. P. Rickman - 2/23/96. No changes in the interim.

5. J. Phillips Director Division of LPS Office of Generic Drugs	1=2 TTA: 41 months.	Date 9/16/96 Initials SP	Date 9/16/96 Initials SP

Comments:
No C.P or legal cases pending; EER now acceptable.

Satisfactory for approval.

6. G.Johnston
Deputy Director
Office of Generic Drugs
Patent Cert - P_4 - Yes N/A No___
Petition status _____
Pend. Legal Actions - Yes___ No ✓
Comments:
3rd approval for this product

Date 9-16-96 Initials G
Date 9-16-96 Initials G

7. D. Sporn
Director
Office of Generic Drugs

R. Williams, MD
1st Generic _____
PD or Clinical for BE _____
Special Scientific or Reg Issues ___
Comments:

Date 9/16 Initials
Date 9/16 Initials

8. Project Manager R. West

Date _____ Initials _____
Date 9/17/96 Initials R. West

Company Notified
_____ Time notified of approval via telephone
1:21 Time notified of approval via facismile

LETTER SIGNED: _____
(Name and Date)

(revision date 8-14-96) (X:\wpfile\welsh\rout2.rec)

ANDA/AADA OFFICE LEVEL ADMINISTRATIVE REVIEW
AND ANDA ACTION LETTER ROUTING RECORD

ANDA #
AADA # 64-081
Drug Cefaclor
Dosage Form Capsules
Strength 250 mg and 500 mg
Applicant Biocraft
Manufacturing Site (s) 8-10
Gloria Lane, Fairfield, NJ
Proposed Action AP TA

Original Rec'd date 2/19/93
Open Amendment Date(s) 9/8, 9/23/1994 and 3/31/95
Chemistry Reviewer Duffy
Supervisor Harrison
Bio Reviewer M. McKary
Supervisor R. Bhatnagar
Patent Certification [illegible]

REVIEWER:	RECEIPT	ACTION
1. Director of Chem. I or (II) Office of Generic Drugs Comments: Chemistry is satisfactory.	Date 1/16/96 Initials [illegible]	Date 2/8/96 Initials [illegible]
2. Office Level Chem Review **(1st Generic Only)** Div. Dir. of Chem I or II (if necessary) Yes __ No (X) Comments:	Date _____ Initials _____	Date _____ Initials _____
3. P. Rickman Supv., Reg. Support Branch	Date 2/16/96 Initials [illegible]	Date 2/23/96 Initials [illegible]

Contains certification required by the GDEA if sub after 6/1/92
Yes ✓ No ___ //// Determination of Involvement? Yes ___ No ✓
Comments:
EER: pending Acceptable EER 9/13/96

Office Level Bio Review Acceptable 12/27/94

4. J. Phillips Act. Dir., Division of LPS Office of Generic Drugs Comments: Satisfactory (pending EER), No Citizens Petition on this product	Date 3/15/96 Initials [illegible]	Date 3/18/96 Initials [illegible]
5. R. Williams, M.D., /CDER C. Ganley, M.D., Acting Dir. Office of Generic Drugs Comments:	Date _____ Initials _____	Date _____ Initials _____

LETTER SIGNED: _____
(Name and Date)

[illegible]vision date 11-24-95) (X:\welsh\rout2.rec)

TO: BOB WEST

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

PPROVAL UPDATE

REQUEST TYPE (Check One) ☐ Original / ☒ FollowUp ☐ FUR	DATE July 18, 1996	PHONE NO. 594-0360	EER ID # 17923
REQUESTORS NAME: R Adams/Jim Wilson	DIVISION:Office of Generic Drugs		MAIL CODE: HFD-643
APPLICATION AND SUPPLEMENT NUMBER: AADA 64-081			
BRAND NAME:	ESTABLISHED NAME: Cefaclor Capsules USP		
DOSAGE STRENGTH: Capsules, 250 mg and 500 mg			STERILE ☐Yes ☒ No~
PROFILE CLASS:: CHG	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*		
APPLICANT'S NAME: Biocraft Laboratories, Inc.			
APPLICANT'S ADDRESS: 18-01 River Road Fair Lawn, NJ 07410			
COMMENT: approvable.			

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY~	
Biocraft Laboratories, Inc. -10 Gloria Lane Fairfield, NJ 07006	Analytical, stability, testing, manufacture drug product	CHG		AC	4/18/95
2	**Manufacturer bulk drug substance**	CSN		AC	5/30/96
3. Biocraft Laboratories, Inc. 92 Route 46 Elmwood Park, NJ	Analytical and stability testing	NEC		AC	5/22/95
4. Biocraft Laboratories, Inc.	Microbiological testing	NEC		AC	6/29/93
5.					

FOR HFD-324 USE ONLY:	CSO	ISI	DATE RECEIVED	7/18/96
	CGMP COMPLIANCE STATUS	Acceptable	DATE	9/13/96

FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
DA 64-081

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

PRE APPROVAL UPDATE

REQUEST TYPE *(Check One)* ☐ Original ☒ FollowUp ☐ FUR	DATE July 18, 1996	PHONE NO. 594-0360	EER ID #
REQUESTORS NAME: R.Adams/Jim Wilson	DIVISION:Office of Generic Drugs		MAIL CODE: **HFD-643**
APPLICATION AND SUPPLEMENT NUMBER: AADA 64-081			
BRAND NAME:	ESTABLISHED NAME: Cefaclor Capsules USP		
DOSAGE STRENGTH: Capsules, 250 mg and 500 mg		STERILE ☐Yes ☒ No~	
PROFILE CLASS:: CHG	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*		
APPLICANT'S NAME: Biocraft Laboratories, Inc.			
APPLICANT'S ADDRESS: 18-01 River Road Fair Lawn, NJ 07410			
COMMENTS : **Biochemica is the subject of a pending OAI Notification (Email dated 6/6/96).** Biocraft has submitted a copy of a July 12, 1996 letter from New Jersey District (M.Mota) stating AADA is approvable.			

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY~	
1. Biocraft Laboratories, Inc.	Analytical, stability, testing, manufacture drug product	CHG			
2.	**Manufacturer bulk drug substance**	CSN			
3. Biocraft Laboratories, Inc. 92 Route 46 Elmwood Park, NJ	Analytical and stability testing	NEC			
4. c.	Microbiological testing	NEC			
5.					

FOR HFD-324 USE ONLY:	CSO		DATE RECEIVED
	CGMP COMPLIANCE STATUS		DATE

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: AADA 64-081

3.1 + FILE IN AADA 64-081

E L E C T R O N I C M A I L M E S S A G E

Date: 10-Jun-1996 02:03pm EDT
From: OCPREAPP Account
OCPREAPP
Dept:
Tel No: FAX t-

Sent By: Joseph David Doleski

TO: Robert West (WESTR)

CC: James Wilson (WILSONJ)

Subject: biocraft

Here is a copy of the recommendation received today:

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MID ATLANTIC REGION
NEW JERSEY DISTRICT

FROM: Matthew H. Lewis, District Director 6/10/96

SUBJ: Application#: 64-081 Supplement#:

TO: Compliance Evaluation Staff, HFD-320
FAX: (301) 594-2202

INFO: MPQAS, HFC-120, (301) 443-4625
Susan Setterberg RFDD/HFR-MA1
Compliance Branch, NWK-DO
Joann Givens, DIB, NWK-DO

PRODUCT: CEFACLOR 250MG & 500MG CAPSULES PROFILE: CHG

APPLICANT: CFN: 2215768
BIOCRAFT LABORATORIES INC
92 RT 46
ELMWOOD PARK, NJ 07407

ESTAB TYPE: MFG

DATE CONCURRENCE REQUESTED: 4/15/96 EI START: 5/09/96 EI END: 6/05/96

DISTRICT RECOMMENDATION: WITHHOLD

COMMENTS:

Development issues included no particle size specifications for drug substance or drug product, impurities found at greater than .1% in the drug substance and problems with fill weights.

_____

Matthew H. Lewis
Director
New Jersey District

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

FILL IN HNDH 64-051

ESTABLISHMENT EVALUATION REQUEST

PRE APPROVAL UPDATE

EST TYPE (Check One)	DATE	PHONE NO.	EER ID #
Original ☒ FollowUp ☐ FUR	April 3, 1995	594-0360	
REQUESTORS NAME: Eric Duffy/Jim Wilson	DIVISION:Office of Generic Drugs		MAIL CODE: HFD-643
APPLICATION AND SUPPLEMENT NUMBER: AADA 64-081			
BRAND NAME:	ESTABLISHED NAME: Cefaclor Capsules USP		
DOSAGE STRENGTH: Capsules, 250 mg and 500 mg			STERILE ☐Yes ☒ No~
PROFILE CLASS:: CHG	PRIORITY CLASSIFICATION (See SMG CDER-4820.3)		
APPLICANT'S NAME: Biocraft Laboratories, Inc.			
APPLICANT'S ADDRESS: 18-01 River Road Fair Lawn, NJ 07410			
COMMENTS : E			

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY~
1. Biocraft Laboratories, Inc.	Analytical, stability, testing, manufacture drug product	CHG		
	Manufacturer bulk drug substance	CSN		
3. Biocraft Laboratories, Inc. 92 Route 46 Elmwood Park, NJ	Analytical and stability testing	NEC		
4. Biocraft Laboratories, Inc.	Microbiological testing	NEC		
5.				

FOR HFD-324 USE ONLY:	CSO	DATE RECEIVED
	CGMP COMPLIANCE STATUS	DATE

FORM FDA 3274 (8/92)
cc: AADA 64-081

Distribution: Original and Yellow Copy: HFD-324.

E L E C T R O N I C M A I L M E S S A G E

Date: 26-Mar-1996 02:13pm EST
From: Regina Brown
RBROWN4@FDAEM@SSWMBX@FDAOC
Dept:
Tel No:

TO: DOLESKI@A1@FDACD

Subject: re: Biocraft

Hi Dave, For application Cephaclor 64-081 I've forwarded an assignment(dt 3/15/96) to IBr and they are scheduling it. I don't believe it actually got inspectional coverage last July, but it did fall into the "we are going to do something about this" recommendation hole...hey, it was fun meeting you at the course. You just can't stop smiling, can you...Regina

E L E C T R O N I C M A I L M E S S A G E

Date: 07-Aug-1995 01:34pm EDT
From: Fermin Simental
SIMENTAL
Dept: HFD-473 FB-8 2024
Tel No: 202-205-4313 FAX 202-205-4940

TO: Mark Anderson (ANDERSONM)
TO: Eric Duffy (DUFFYE)

CC: Joseph Hanig (HANIG)
CC: Almetia Hoskins (HOSKINS)
CC: Richard Hogart (HOGART)

Subject: Cefaclor Capsules AADA 64-081 (95-730-587 & 95-730-589)

Mark,

Sorry for the delay in replying to your inquires concerning cefaclor capsules, AADA 64-081 (95-730-587 & 95-730-589). I wanted to complete the report and at the same time get a little more background on previous analysis done on cefaclor bulk.

. seems that another Pharmaceutical Company submitted two methods to be validated. One method, isocratic, was used for purity determination and the second method, gradient, was used for the positive identification and quantitation of an unusally degraded sample.

It seems that this company developed this gradient method primarily to resolve several unidentified earlier eluting impurities resulting from degradation which would otherwise not be separated from each other in the isocratic mode.

The gradient method also hastens the elution on of a late eluting impurity.

The degradation impurities may appear in cefaclor bulks after long storage.

None of the impurities interfere with the main cefaclor peak nor the peak in either of the two mehtods.

Thanks for your patience

Fermin Simental

Richard M. Hogart

E L E C T R O N I C M A I L M E S S A G E

Date: 07-Aug-1995 12:41pm EDT
From: Fermin Simental
SIMENTAL
Dept: HFD-473 FB-8 2024
Tel No: 202-205-4313 FAX 202-205-4940

TO: Mark Anderson (ANDERSONM)

CC: Eric Duffy (DUFFYE)
CC: Joseph Hanig (HANIG)
CC: Almetia Hoskins (HOSKINS)
CC: Richard Hogart (HOGART)

Subject: Cefaclor Capsules AADA 64-081

Chemistry Review Notes
August 2, 1995

Re: Form AADA 64-081
Sample 95-730-587 & 95-730-589
Cefaclor Capsules 250 mg and 500 mg
Submitted by: Biocraft Laboratories
Fairfield, NJ 07004

Biocraft Laboratories submitted a Form 6 for method validation on two exhibit lots of Cefaclor capsules, 250 mg and 500 mg respectively.

The method to be validated was the method published in the Pharmacopeal Forum, Volume 18, Number 4, July-August 1992.

The method describes the analysis as resolving two peaks, Cefaclor with retention time of approximately 23 minutes and or with a retention time of approximately 29 minutes and a resolution factor between peaks of not less than 2.0 when a resolution solution of equal concentrations, 0.05 mg/ml, is injected and chromatographed.

The resolution solution consisted of a measured amount of Cefaclor and a measured amount of or diluted to give a concentration of 0.05 mg/ml.

The analysis was carried out following the instructions given in the monograph.

The Gradient System consisted of:
Solvent:

Mobile Phase A: ate.

Page(s) 4

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable.

8/7/95

raw data; methods; chemistry

HFD-643

DATE: APR 13 1995

TO: Director, Newark District, HFR-MA300

FROM: Chief
Investigations & Compliance Evaluation Branch, HFD-324

SUBJ: 10-Day Notification
AADA 64-081, Cefaclor
Capsules, 250 & 500 mg

PROFILE: NEC

REVIEWER: Eric Duffy
TELEPHONE: 301-594-0360

Applicant:
Biocraft Laboratories Inc.
8-10 Gloria Lane
Fair Lawn, NJ 07410

Establishment:
Biocraft Laboratories
92 Route 46
Elmwood Park, NJ

CFN#: 2215768

The subject application, involving activities at the establishment(s) in your District, specified above, is at an early stage in the approval process. The application provides for this establishment to **perform analytical and stability testing for** the above listed drug product. Based upon the current Quality Assurance Profile, CDER does not intend to assign a pre-approval inspection, and knows of no reason why approval of the application should be withheld. If you have concerns about the state of GMP compliance for this particular site, or operation, an inspection should be scheduled now rather than waiting until the application is at the final approval stage.

We will delay or withhold approval if warranted by ongoing inspection activities as provided in the memo of February 14, 1990 from the Director, Office of Compliance, CDER to all Districts, subject to "Procedure to request evaluations from Districts for all NDA/ANDAs".

Within 10 days, please advise the undersigned by FAX (301-827-0145) or EMS whether or not approval should be withheld or delayed. Your reply should be in the prescribed format and provide your rationale as well as planned timeframes for inspection and correction. Recommendations to withhold approval should be supported by EIR and exhibits sent to HFD-324 **within 30 days.**

Thank you for your attention.

for Mark A. Lynch

Priority: **AADA Pending**
Target Completion: APR 22 1995

cc:

DATE: APR 13 1995

TO: Director, Newark District, HFR-MA300

FROM: Chief
Investigations & Compliance Evaluation Branch, HFD-324

SUBJ: 10-Day Notification
AADA 64-081, Cefaclor
Capsules USP
250mg & 500mg

PROFILE: CHG

REVIEWER: E.Duffy/J.Wilson
TELEPHONE: 301-594-0360

Applicant:
Biocraft Laboratories, Inc.
1801 River Road
Fair Lawn, NJ 07410

Establishment:
Biocraft Laboratories
8-10 Gloria Lane
Fairfield, NJ 07006

CFN#: 2245641

The subject application, involving activities at the establishment(s) in your District as specified above, is nearing the early stage in the approval process. The application provides for this establishment to **manufacture and perform analytical and stability testing** for the above listed drug product. If you have concerns about the state of GMP compliance for this particular site, or operation, an inspection should be scheduled now rather than waiting until the application is at the final approval stage.

We will delay or withhold approval if warranted by ongoing inspection activities as provided in the memo of February 14, 1990, from the Director, Office of Compliance, CDER to all districts, subject to "Procedure to request evaluation from districts for all ANDA/NDAs".

Within 10 days, please advise the undersigned by FAX (301-827-0145), or EMS, whether or not approval should be withheld or delayed. Your reply should be in the prescribed format and reference **AADA 64-081**. Recommendations to withhold approval should be supported by EIR and exhibits sent to HFD-324 **within 30 days**.

Thank you for your attention.

for Mark A. Lynch

Priority: **AADA pending**
Target Completion: APR 22 1995
cc:

ANDA Approval Summary

64-081 — ANDA Number
Riocraft Laboratories — Applicant Name

Established Name of Drug	Dosage Form	Strength	Container size(s)
Cefaclor Capsules USP	Capsules	250 and 500 mg	15, 100 + 500's

	Date Found Satisfactory	Comments
Labeling	2/28/95	See label worksheet
Chemistry, Manufacturing, and Controls	10/19/95	See Chem Rev # 4
GMP's		
Manufacturer - Finished Dosage Form		
Outside Facilities		
Manufacturer(s) - Active Ingredient(s)		

Chemist Reviewer — 1/3/96 — Date — Branch Chief — 1/5/96 — Date

Petition Required — No ☒ — Yes ☐

Listed Drug Information 505(j)(2)(A)	N/A Title II Drug Product	
Patent Certification 505(j)(2)(B)		
Date Patent/Exclusivity Expires (if applicable)		

Bioequivalence Section

	No	Yes	DB	DGD		
Dissolution Required?	☐	☑	☐	☐		
In vivo study(s) required?	☐	☑			500 mg	
Study(s) Found Acceptable					12/20/94	
Waiver Request Granted					12/20/94	250 mg cap
Total Bioequivalence Requirement Met					12/20/94	

/S/ — Administrative Reviewer — 2/23/96 — Date

Approved

Disapproved ☐

Director, Office of Generic Drugs — Date

Comments:

DATE: APR 13 1995

TO: Director, Newark District, HFR-MA300

FROM: Chief
Investigations & Compliance Evaluation Branch, HFD-324

SUBJ: 10-Day Notification
ANDA 64-081, Cefaclor
Capsules USP
250mg & 500mg

Applicant:
Biocraft Laboratories, Inc.
1801 River Road
Fair Lawn, NJ 07410

PROFILE: NEC

REVIEWER: E.Duffy/J.Wilson
TELEPHONE: 301-594-0360

Establishment:
Biocraft Laboratories, Inc.
12 Industrial Park
Waldwick, NJ

CFN#: 2227185

The subject application, involving activities at the establishment(s) in your District, specified above, is at an early stage in the approval process. **The application provides for this establishment to test the above listed drug product.** If you have concerns about the state of GMP compliance for this particular site, or operation, an inspection should be scheduled now rather than waiting until the application is at the final approval stage.

We will delay or withhold approval if warranted by ongoing inspection activities as provided in the memo of February 14, 1990 from the Director, Office of Compliance, CDER to all Districts, subject to "Procedure to request evaluations from Districts for all NDA/ANDAs".

Within 10 days, please advise the undersigned by FAX (301-827-0145) or EMS whether or not approval should be withheld or delayed. Your reply should be in the prescribed format and provide your rationale as well as planned timeframes for inspection and correction. Recommendations to withhold approval should be supported by EIR and exhibits sent to HFD-324 **within 30 days**.

Thank you for your attention.

/S/

for/ Mark A. Lynch

Priority: **ANDA pending**
Target Completion: APR 22 1995
cc:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

M

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE *(Check One)* ☒ Original ☐ FollowUp ☐ FUR	DATE July 13, 1994	PHONE NO. 594-0360	EER ID # 16638
REQUESTORS NAME: Eric Duffy/Jim Wilson	DIVISION:Office of Generic Drugs		MAIL CODE: **HFD-643**
APPLICATION AND SUPPLEMENT NUMBER: AADA 64-081			
BRAND NAME:	ESTABLISHED NAME: Cefaclor Capsules USP		
DOSAGE STRENGTH: Capsules, 250 mg and 500 mg		STERILE ☐Yes ☒ No~	
PROFILE CLASS:: CHG	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*		
APPLICANT'S NAME: Biocraft Laboratories, Inc.			
APPLICANT'S ADDRESS: 18-01 River Road Fair Lawn, NJ 07410			
COMMENTS : Please pick up samples from lots 52064 & 52010 Top 200 send to ADB- Washington			

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY~	
	Analytical, stability, testing, manufacture drug product	~~NEC~~ CHG	BICF 16732	UN	7/22/94
2	Manufacturer bulk drug substance	~~NEC~~ /	BCOM 16733	CA	8/8/94
3. Biocraft Laboratories, Inc. 92 Route 46 Elmwood Park, NJ	Analytical and stability testing	NEC	BILE 16734	UN	7/22/94
	Microbiological testing	NEC	BLLW 16735	UN	7/22/94

FOR HFD-324 USE ONLY:	CSO /S/	DATE RECEIVED	7/26/94
	CGMP COMPLIANCE STA /S/	DATE	8/8/94

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: AADA 64-081

E L E C T R O N I C M A I L M E S S A G E

Date: 27-Jul-1994 11:55am DST
From: Mark Lynch
LYNCHM
Dept: HFD-324 MPN1 266
Tel No: 301-594-0098 FAX 301-594-2202

TO: Robert West (WESTR)

CC: James Wilson (WILSONJ)
CC: Melissa Egas (EGASM)
CC: Michelle Burt (BURTM)
CC: Joseph David Doleski (DOLESKI)
CC: John Dietrick (DIETRICKJ)
CC: Barry Rothman (ROTHMANB)
CC: Doug Ellsworth (ELLSWORTHD)

Subject: Biocraft Injunction - Re Pending Applications

We have been advised by HFD-325, J. Dietrick, that Biocraft Labs., signed Consent Decree of Permanent Injunction last Friday, July 22, 1994. This affects their U.S. sites' GMP compliance. We do not anticipate that we will be in a position to approve any applications until they have certified that they are in GMP compliance, have made substantial corrections, and the districts involved have an opportunity to verify by inspection that corections have been effectively made. We expect that this may take 6-9 mos. perhaps longer. John Dietrick says look at the Barr example that has gone on a year.

We intend to return EERs on file for this firm because it doesn't make sense to keep communicating with the district about this until it has been resolved. We will not rescind requests we have made to HFC-134 to schedule foreign inspections, so expect that these will be done at a time when we are in a position to reconsider Biocraft's GMP compliance status under the terms of the injuction. I think we could again begin receiving EERs for Biocraft about 10 days (2 wks.) prior to the time we anticipate GMPs will again be acceptable. This will have to be indicated by HFD-325 and will be some time after the district has performed an audit inspection that is NAI.

HFD-325 will forward copies of the court order, once OC receives copies, if you need it to base Not Approvable letters on. Please advise.

all sites except for bulk sterility in NJ & Michigan

E L E C T R O N I C M A I L M E S S A G E

Date: 04-Aug-1994 10:23am DST
From: Mark Lynch
LYNCHM
Dept: HFD-324 MPN1 266
Tel No: 301-594-0098 FAX 301-594-2202

TO: Robert Pollock (POLLOCK)

CC: Gordon Johnston (JOHNSTON)
CC: Doug Sporn (SPORN)
CC: James Wilson (WILSONJ)
CC: Robert West (WESTR)
CC: Janine Davis (DAVISJA)

Subject: Biocraft Injunction Provisions

This is a summary of the provisions of the Biocraft Injunction provided by HFD-325. As discussed in the status meeting we will be returning the EERs that are affected.

If you need something more formal than this let me know. Also, when the terms of the injuction are complied with, we can begin to process EERs for them again. HFD-325 will or the the district (NWK) will have to notify us when that is anticipated and completed.

E L E C T R O N I C M A I L M E S S A G E

Date: 04-Aug-1994 09:41am DST
From: John Dietrick
DIETRICKJ
Dept: HFD-325 MPN1 266
Tel No: 301-594-0098 FAX 301-594-2202

TO: Mark Lynch (LYNCHM)
TO: Barry Rothman (ROTHMANB)

CC: Raymond Hamilton (HAMILTONR)
CC: Bruce W. Hartman (HARTMANB)

Subject: Biocraft Consent Decree/approvals

Barry asked me to send you the following information on Biocraft so that you could advise OGD regarding application approvals and EERs.

The Biocraft consent decree requires Biocraft to cease distribution of 4 drugs until an outside expert certifies that the manufacturing processes are validated, laboratory methods are validated, a stability plan is in effect, a failure investigation procedure is in effect, analysts are certified, and GMPs are followed.

Five additional drug products must be certified in the same manner within 30 days, and another 6 drugs within 120 days, and the remaining drugs and all facilities and procedures are in compliance, within 6 months from the date of the decree.

The decree also requires the recall of all in date batches of certain products which had high failure rates, and of selected batches of other products which had testing discrepancies.

All expert certifications are subject to review and acceptance by FDA, with inspections to verify corrections if necessary.

When the firm certifies that all processes and all procedures are in compliance, the district will conduct a general GMP inspection. The decision to resume application approvals and change the profile to acceptable, will depend on that inspection. According to the dates in the decree, this should occur within 6 months, but could be extended or occur earlier.

The consent decree applies to the finished dosage facilities in paterson, Fairfield, and Fair Lawn, NJ. It does not apply to the bulk facilities in Elmwood Park, NJ, or Missouri.

E L E C T R O N I C M A I L M E S S A G E

Date: 04-Aug-1994 10:32am DST
From: Robert Pollock
POLLOCK
Dept: HFD-632 MPN2 102
Tel No: 301-594-0315 FAX 301-594-0183

TO: Mark Lynch (LYNCHM)

CC: Gordon Johnston (JOHNSTON)
CC: Doug Sporn (SPORN)
CC: James Wilson (WILSONJ)
CC: Robert West (WESTR)
CC: Janine Davis (DAVISJA)

Subject: RE: Biocraft Injunction Provisions

Mark,

It would help if two additional pieces of information were added:

1. The date of the consent decree so we could cite it in our NA letter.

and,

2. A definitive statement from you that the problems are systemic in nature and apply to all biocraft finished dosage forms.
(its kinda in there but a crisp statement would be helpful)

Thanks

Bob

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT EVALUATION REQUEST

APPROVAL UPDATE

REQUEST TYPE *(Check One)* ☐ Original ☒ FollowUp ☐ FUR	DATE April 3, 1995	PHONE NO. 594-0360	EER ID #
REQUESTORS NAME: Eric Duffy/Jim Wilson	DIVISION:Office of Generic Drugs		MAIL CODE: HFD-643
APPLICATION AND SUPPLEMENT NUMBER: AADA 64-081			
BRAND NAME:	ESTABLISHED NAME: Cefaclor Capsules USP		
DOSAGE STRENGTH: Capsules, 250 mg and 500 mg			STERILE ☐Yes ☒ No
PROFILE CLASS:: CHG	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*		
APPLICANT'S NAME: Biocraft Laboratories, Inc.			
APPLICANT'S ADDRESS: 18-01 River Road Fair Lawn, NJ 07410			
COMMENTS :			

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY
Biocraft Laboratories, Inc.	Analytical, stability, testing, manufacture drug product	CHG		
2.	Manufacturer bulk drug tance	CCS		
3. Biocraft Laboratories, Inc. 92 Route 46 Elmwood Park, NJ	Analytical and stability testing	NEC		
4. Biocraft Laboratories, Inc.	Microbiological testing	NEC		
5.				

FOR HFD-324 USE ONLY:	CSO	DATE RECEIVED
	CGMP COMPLIANCE STATUS	DATE

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.
cc: AADA 64-081

MEMORANDUM

TELEPHONE CONFERENCE

ANDA/DRUG: **64-081/ Cefaclor**

SPONSOR: **BioCraft**

DATE: 9/22/94

PHONE: **(201) 703-0400**

BETWEEN: **Bruice Bardoni**

and

Jason A. Gross (FDA)

==========

The firm did not submit a computer diskette with their submission.

9/22/94
Firm called message left to return my call.

9/22/94
Informed the firm that a data diskette was required for this application

9/28/94
Disk was sent by FED-EX

REQUEST TYPE (Check One) ☑ Original ☐ FollowUp ☐ FUR	DATE July 13, 1994	PHONE NO. 594-0360	EER ID # 10638
REQUESTORS NAME: Eric Duffy/Jim Wilson	DIVISION: Office of Generic Drugs		MAIL CODE: HFD-643
APPLICATION AND SUPPLEMENT NUMBER: AADA 64-081			
BRAND NAME:	ESTABLISHED NAME: Cefaclor Capsules USP		STERILE ☐Yes ☒ No
DOSAGE STRENGTH: Capsules, 250 mg and 500 mg			
PROFILE CLASS:: CHG	PRIORITY CLASSIFICATION (See SMG CDER-4820.3)		
APPLICANT'S NAME: Biocraft Laboratories, Inc.			
APPLICANT'S ADDRESS: 18-01 River Road, Fair Lawn, NJ 07410			
COMMENTS : Please pick up samples from lots 52064 & 52010 TOP 200 send to ADB - Washington			

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY -	
1. Biocraft Laboratories, Inc.	Analytical, stability, testing, manufacture drug product	~~NEC~~ CHG	BICF 16732	UN	7/22/94
2	Manufacturer bulk drug substance	~~NEC~~?	COM 16733	CA	8/8/94
3. Biocraft Laboratories, Inc. 92 Route 46 Elmwood Park, NJ	Analytical and stability testing	NEC	BILE 16734	UN	7/22/94
4. Biocraft Laboratories, Inc.	Microbiological testing	NEC	BILW 16735	UN	7/22/94
5.					

FOR HFD-324 USE ONLY:

CGMP COMPLIANCE STATUS /S/ /S/

RECEIVED 7/20/94

DATE 8/8/94

FORM FDA 3274 (8/92) Distribution: Original and Yellow Copy: HFD-324.

cc: AADA 64-081

LABELING REVIEW WORKSHEET

FIRM: Biocraft ANDA(s) 64-081
DRUG: Cefaclor Capsules USP, 250 mg and 500 mg

LABELING OF THE LISTED DRUG

FIRM: Eli Lilly Industries Inc. NDA#: 50-521; 50-522
APPROVAL DATE: May 25, 1993 REV. DATE: Feb 12, 1993

CONTAINER LABELS

APPRCVED COPY ON FILE? ✓ Y N DATE
USP CONTAINER/CLOSURE REQUIREMENTS: Preserve in tight containers

RECOMMENDED STORAGE STATEMENT:
ANDA: CRT plus uses CRC on 15's and 100's, Keep tightly closed new, Avoid excessive
NDA: CRT; (CRC for 15 and 100's) Store at room temperature in 50's
OTHER KEY ISSUES: Usual adult Dosage 250 mg, Three times a day. For Severe infections, the dosage may be doubled. See accompanying literature.

INSERT LABELING

PATENT & EXCLUSIVITY ISSUES: none

BIO ISSUES: Pending

ALL INACTIVE INGREDIENTS CITED? ✓ Y N
OTHER KEY ISSUES: ~~none~~ The approval is based on the insert Received Feb 12, 1993 because the approval of the NDA for 95 has a version date of Nov. 91 and the Nov 1991 date - not ~~this~~ not the most current Supt. The May 28, 1993 approval supercedes the Dec. 1993 approval in the MIS system Done 10/11/95

APPROVAL SUMMARY

CONTAINER LABELS (SUBMISSION DATE): May 12, 1994 SPL for 250 mg (15, 100, 500's); 500 mg (15, 100, 500's)
CARTON LABELING (SUBMISSION DATE): none
INSERT LABELING (SUBMISSION DATE): May 12, 1994
FORMULATION/SCORING SUMMARY: Capsules
COMMENTS OR FUTURE REVISIONS NEEDED: encourage ~~the Box~~ Color contrast for the 500 mg Box. Please note that the 500 mg is differentiated from the 250 mg strength by the use of a box.

DATE: 6/21/94 REVIEWER: Angela M. Gray
SUPERVISOR: Tony Phillips 6/27/94

REV. 2/93; WP: WORK.293;JP

acceptable per APayne 2/28/95 and Jerry Phillips 3/28/95

REVIEW OF PROFESSIONAL LABELING

AADA

DRAFT

DATE OF REVIEW: September 17, 1993

ANDA #: 64-081

NAME OF FIRM: Biocraft

NAME OF DRUG: Cefaclor Capsules USP, 250 mg and 500 mg

DATE OF SUBMISSION: February 19, 1993

FOR THE RECORD

1) A *labeling letter out* was sent to firm separate from the chemistry letter (see Letter to firm).

2) This review was based upon the labeling of CECLOR® (Lilly; Revised: February 12, 1993; Approved: May 28, 1993; Code: 2770 AMP).

3) *Storage*
NDA: CRT 15°-30°C (59°-86°F)
AADA: CRT 15°-30°C (59°-86°F)

4) *Container* 15's, White HDPE with CRC; 100's and 500's, HDPE with non-CRC.

5) The firm has proposed a new package size (500's) which the innovator does not have. This package size (15's) is marketed by the innovator.

Cathy Shannon 9-22-93

cc:

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

BIOCRAFT
1801 RIVER RD
FAIR LAWN NJ 07410

AADA N064081

Dear Sir/Madam:

We acknowledge the receipt of your Abbreviated Antibiotic Drug Application submitted pursuant to Section 507 of the Federal Food, Drug, and Cosmetic Act for the following:

NAME OF DRUG:
CEFACLOR capsules USP, 250mg, 500mg

DATE OF APPLICATION: 19-FEB-93

DATE OF RECEIPT: 03-MAR-93

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the number shown above.

Send representative samples, three times the amount needed to perform all pendial (CFR/USP) tests except pyrogens and sterility tests, from three ches along with the respective certificates of analysis and copies of batch records. The exhibit samples should be from batch sizes that are minimally 15%-20% of the maximum production size and manufactured in production equipment. Send the samples to:

FDA/Division of Research and Testing
Attention: Joseph H. Graham, Ph.D. (HFD-473)
Chief, Antimicrobial Drugs Branch
200 C Street, S.W., Room 2002
Washington, D.C. 20204

Send copies of all correspondence regarding the requested samples to the AADA.

We recommend that you send the samples by registered mail/return receipt requested.

Sincerely yours,

Harrison
Roger L. Williams, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

-473 (Dr. Joseph H. Graham)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION

File on open Volume

ESTABLISHMENT EVALUATION REQUEST

REQUEST TYPE *(Check One)*	DATE	PHONE NO.	EER ID #
☒ Original ☐ FollowUp ☐ FUR	July 13, 1994	594-0360	

REQUESTORS NAME: Eric Duffy/Jim Wilson	DIVISION:Office of Generic Drugs	MAIL CODE: HFD-643

APPLICATION AND SUPPLEMENT NUMBER:
AADA 64-081

BRAND NAME:	ESTABLISHED NAME: Cefaclor Capsules USP

DOSAGE STRENGTH: Capsules, 250 mg and 500 mg	STERILE ☐Yes ☒ No~

PROFILE CLASS:: CHG	PRIORITY CLASSIFICATION *(See SMG CDER-4820.3)*

APPLICANT'S NAME: Biocraft Laboratories, Inc.

APPLICANT'S ADDRESS: 18-01 River Road
Fair Lawn, NJ 07410

COMMENTS : Please ~~Send~~ pick up samples from Lots 52067 & 52010 - Send to ADR - Washington

FACILITIES TO BE EVALUATED

(Name and Complete Address)

	RESPONSIBILITY	DMF NUMBER/ PROFILE CODE	FKEY CIRTS ID	HFD-324 USE ONLY ~	
1. Biocraft Laboratories, Inc.	Analytical, stability, testing, manufacture drug product	NEC			
2.	Manufacturer bulk drug substance	NEC			
3. Biocraft Laboratories, Inc. 92 Route 46 Elmwood Park, NJ	Analytical and stability testing	NEC			
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